

SUMMARY OF SAFETY AND EFFECTIVENESS

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I. General Provisions

Common or Usual Name: PTA Balloon Catheter

Proprietary Name: Opta 5™ PTA Balloon Catheter

II. Name of Predicate Devices

Cordis Opta 5™ PTA Balloon Catheter
Cordis Mega PTA Balloon Catheter
Meditech Ultra-Thin™/Blue Max Balloon Catheter
Cook Accent® Balloon Angioplasty Catheter

III. Classification

Class II

IV. Performance Standards

Performance standards have not been established by the FDA under section 514 of the Food, Drug and Cosmetic Act.

V. Intended Use and Device Description

The Cordis Opta 5™ PTA Balloon Catheter is intended to dilate stenoses in peripheral arteries and is applied to the iliac, femoral, ilio-femoral, popliteal, infra popliteal and renal arteries.

The Cordis Opta 5™ PTA Balloon Catheter is a coaxial design with a distal inflatable balloon. Two radiopaque marker bands indicate the dilating section of the balloon and aid in balloon placement. The catheter tip is tapered to ease entry into peripheral arteries and to facilitate the crossing of tight stenoses.

The recommended working pressure range for the balloon is between the nominal size pressure and the rated burst pressure. 3mm through 10mm diameter balloons reach their nominal size between 5 and 6 atm internal pressure. The 12mm diameter balloons reaches its nominal size between 3 and 4 atm internal pressure. All balloons distend to sizes above the nominal size at pressures greater than the nominal size pressure range.

The injectate lumen is used to deliver contrast medium by using a 10-cc syringe, hand injection only (150 psi maximum), and to track the catheter over a prepositioned guidewire. The compatible guidewire size, catheter shaft French size and catheter length are printed on the injectate lumen hub.

The inflation lumen is used to inflate and deflate the balloon. The nominal balloon size is printed on the balloon lumen hub.

VI. Biocompatibility

All materials used in the Opta 5™ PTA balloon catheter are biocompatible.

VII. Summary of Substantial Equivalence

The Cordis Opta 5™ PTA Balloon Catheter and the referenced current Cordis Opta 5™ PTA Balloon Catheter, Cordis Mega PTA Balloon Catheter, Meditech Ultra-Thin™/Blue Max Balloon Catheter and Cook Accent® Balloon Angioplasty Catheter are similar in their basic design, construction, indication for use and performance characteristics.